

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of: Palpu PUSHPANGADAN  Serial No.: 09/846,270  Filed: February 2, 2001  <i>For: Safe, eco-friendly, health protective herbal colours and aroma useful for cosmaceutical application.</i>	Group Art Unit: 1617  Examiner: Wells, Lauren Q    Attorney Docket No: 056859- 0126
--	--

To,  
The Assistant Commissioner for Patents  
Washington, D.C. 20231

**Declaration Under 37 C.F.R. § 1.132**

I, Palpu Pushpangadan age 60 years , residing at, National Botanical Research Institute (NBRI), Lucknow, INDIA, and a citizen of India, do hereby state as under.

I am a Scientist at, National Botanical Research Institute (NBRI), Lucknow, INDIA. I graduated in the year 1965 from Kerala University (Trivandrum, Kerala, India) . I completed my Master's Degree in Botany (Aligarh Muslim

BEST AVAILABLE COPY



University, Aligarh, INDIA), in the year 1968. Subsequently, I completed my doctoral degree in Botany (Medicinal and Aromatical Plants study on inheritance of secondary metabolites of medicinal and aromatic plants from Aligarh Muslim University, Aligarh, INDIA). After completing my doctoral degree, I took up my first assignment as a post-doctoral scientist with the Regional Research Laboratory, Jammu, (Council for Scientific & Industrial Research, INDIA), 1975 – 1992, Tropical Botanical Gardens & Research Institute, Trivandrum, 1992 – 1999, worked in the field of Cytogenetics Ethnomedicine and Ethnopharmacology. After that, I joined the National Botanical Research Institute, Rana Pratap Marg, Post Box No 436, Lucknow-226 001 (INDIA) in 1999, a constituent institution of the Council of Scientific and Industrial Research, India, where I am continuing to now work on Ethnomedicine and Ethnopharmacology for the last 5 years. Presently, I am working as the Director of this institute since 1999.

One of the projects undertaken by NBRI, Lucknow, INDIA is *"Safe, eco-friendly, health protective herbal colours and aroma useful for cosmaceutical application"*. This project was undertaken in the year 1999. The scientists involved in the study were myself Shanta Mehrotra, Ajay Kumar Singh Rawat, sayyada Khatoon, Raghvan Govindarajan. I am the main scientist (project leader) in this study. I am aware of US patent application No. 09/846,270 filed in respect of this project. I am also aware and familiar with all the office actions, objections of the Examiner and the references cited by the Examiner. Therefore, I am completely and fully aware of all the facts relating to this project as well as the present patent application.

**I wish to state at the outset that the challenge in the objective set out by the inventors is develop a safe, eco-friendly, health protective cosmaceutical application. This is not an herbal medicine, nor is this a dermatological treatment. The present invention is a natural cosmetic like lipstick, etc.**

NOT AVAILABLE COPY

A cosmetic is defined as a "toiletry designed to beautify the body". A toiletry developed from natural plants has not been defined in any of the prior arts. The basic fundamentals of Shultz *et al* are a dermatologic medicine. Technically and grammatically, and in common terms, a dermatologic medicine is different from a cosmaceutical composition. The use and application of essential oils refereed in the present invention are different from that of the prior arts. The citation of Schultz et al is titled "Method and composition for the treatment of dermatologic diseases", whereas the title of the present invention is "*Safe, eco-friendly, health protective herbal colours and aroma useful for cosmaceutical application*". The title is very explicitly stating a different aim and application of the present invention.

The invention of Schultz et al. uses the essential oil as a excipient and not as a medicine, nor does it use the oil as cosmaceutical ingredients. It is claimed in claim 8 of this art that the use of the essential oil is to enhance the therapeutic effect of active ingredient. Wherein, in the present invention the essential oils (used singly or as blends of 2 or more natural essential oils or its isolates) constitutes as ingredients of the cosmaceutical composition. The essential oils are being used to elicit certain functional attributes of herbal colorants, i.e. to make them appear brighter in appearance. There is no suggestion in the prior art that the essential oil has cosmaceutical usage.

The present invention does not refer a treatment for dermatological diseases/defects.

The inventors wish to state very explicitly that the present invention is not intention to function as medical treatment/therapeutic medicine. The present invention was aimed at inventing and deriving herbal colors to be used a lipstick,etc. The essential oils used are not used for their medicinal benefits but as facilitators, which have not explored earlier for such preparations.

BEST AVAILABLE COPY

The invention of Tu et al, yet again points out towards a cream against acne and other skin disease caused by fungal infections. In other words this invention has therapeutic protection and not cosmaceutical protection. It is not possible to imagine a cosmaceutical composition from any of the prior arts, as none of the prior arts teach a **HERBAL COSMETIC**. There is no teaching from any of the prior arts about an herbal cosmetic composition. The main ingredients of the present invention are the colored extracts not only from the plants of family Boraginaceae but also from other families like Bixaceae, Fabaceae, Euphorbiaceae etc. The plant *Macrotomia* as described in the prior art of Tu et al is being used for skin-protection cream. A skin protection cream as described by Tu et al, is inhibitory to skin infection by fungus and has therapeutic value. There is neither suggestion nor any teaching in the prior art that herbal color of plant extract can be used as a color for lipstick, color for eye-shadow, color for glow-glitters, as moisturizer, or rouges. In technical terms and generally speaking none of the latter aspects are similar to former aspects. A simple question to understand here is can a dermatological cream be used for beautifying skin? In fact the term cosmetic as used by Tu et al. do not meet the standards of commercial cosmetic. On the other hand Tu's invention regards a skin cream of therapeutic nature. Thus, in itself this very specific and does not teach the aim of the present invention.

There is no teaching in the prior arts, where it states, that a plant attribute as therapeutic agent, would make it obvious to the person skilled in the art to identify its another attribute, which is not therapeutic, but has commercial implication as commercial cosmetic. It cannot be believed that all plants of the same family may have same functions, nor it can be believed that a plant may have more than one function unless proved by experimental studies. The inventors wish to further say that the genera of Boraginaceae viz. *Onosma*, *Arnebia*, *Maharanga*, *Macrotomia*, *Lithospermum*, *Alkanna*, *Anchusa* have colourants but the genus *Cordia*, *Heliotropium* and *Trichogdesma* of the same family Boraginaceae do not have colour. Similarly the roots of genus *Jatropha* of

BEST AVAILABLE COPY

family Euphorbiaceae has colourant but other taxa of Euphorbiaceae viz. *Phyllanthus*, *Euphorbia* and *Croton* do not have colourant. This example very conspicuously proves, the fact, that it is not natural or obvious to believe/presume that the attributes of present invention have its origin from the prior arts, as they different.

The present invention is not motivated from any of the prior arts because OF following reasons:

- (a) The therapeutic application has medicinal benefits and is used against disease ailments. This is the aim of the both prior arts (i.e. Tu and Schultz). The Examiner should know the difference that a therapeutic application cannot be imagined to have a cosmetic application especially as herbal colorant. Further, none of the prior arts have identified the genera *Onasma*, *Amebia*, *Maharanga*, *Macrotomia*, *Lithospermum*, *Alkanna*, *Anchusa* of Boraginaceae as the best source of colourants for cosmetics like lipstick, eye shadows and glow glitters. Where in the present invention the other sources of herbal colours are *Bixa*, *Butea*, *Carthamus*, *Hibiscus*, *Jatropha*, *Nyctanthes*, *Rhododendron*, and *Tagetes* etc.

Although, Tu does disclose about plant *Macrotomia*, but it relates to therapeutic application. This does not suggest that all plants of this family have an application as herbal colorant, including *Macrotomia*. A person skilled in the art cannot and will not assume the whole family can function as cosmaceutical from a single plant. This is only arrived after much of study and experimentation, which would mean unprecedented application of manpower, energy and time. A simple example the applicant wish to provide is that of plant *Azadirachta indica* and *Melia* sp, The plant *Azadirachta* has so many applications in medicine, whereas the plant *Melia* belonging to the same family

BEST AVAILABLE COPY

does not have such an application. Similarly, *Rauwolfia serpentina* and *Holarrhena antidysenterica* have many medicinal value but *Carissa carandus* and *Ichnocarpus* belong to the same family Apocynaceae, do not have so much application. Likewise *Allium* species i.e. Garlic and Onion have so much medicinal values but *Lilium* species are mostly ornamental. Both the genus belong to the same family Liliaceae the another example is the orchids where *Malaxi accuminata* and *Microstylis* have much medicinal value but *Dendrobium* & *Bulbophyllum* species do not have medicinal value only ornamentals, belong to the same family Orchidaceae. Similarly, not only the members of same family but the plants belong to the same genera have different medicinal properties. The examples are as follows;

- The roots of *Coeus forskohlii* and whole plant of *C. ambonicus* have medicinal properties but other ornamental *Coleus* species does not have any medicinal properties.
- *Viola odorata*, *Viola pilosa* commonly used remedy for cough and cold in Unani system of medicine but *Voila tricolor* is well known ornamental plant without any medicinal properties.
- *Cassia senna*, *Cassia angustifolia* are used for the isolation of sennosides (as a laxative) but *C. siamea*, *C. acutifolia* do not have so much medicinal value.

Therefore, its imperative to undertake experimental studies to establish functions or attributes for any plant. By mere observing the same plant in one invention does not establish its function for all areas of attributes. This can only be achieved after through analysis and functions.

- (b) The Examiner contends that the prior arts teach composition for skin benefit similar to the present invention. The term "skin benefit" needs to be understood in its totality, i.e this term is used when we are talking in context of about therapeutic, which is only brought about by a

medicine or medicinal extract. This is different than an application which is a cosmetic application. Cosmetics are not used for any benefits of skin; its primary role is beautifying the person. A person would not be motivated to use the creams described in the prior arts for looking beautiful, nor the creams of prior art will not give color to the skin, lips, eyes/ etc. Further, Tu's contention of skin becoming rosy and tender is only after treatment with medicinal cream, i.e brought only under the circumstances when fungal infection is removed and there is appearance of rosy and tender skin, this is not beautification. In present invention the colourant has been specially used as beatifying agents for lips, cheeks, and eyes. The colourant has different shades viz. purplish red, cerise, ruby red, beet root purple, dark violet, deep blue, blackish blue, pastel red, pale red, purplish red, rose red, cerise, ruby red, deep magenta, beet root purple, amaranth, dark purple, dark violet, deep violet, deep blue and blackish blue. The colourant are also favorable for chapped lips and may be used on de-pigmented area of lips.

- (c) The prior art of Tu mentions the use of therapeutic extract from the roots of *Macrotomia*. This means that the medicinal value lays within the roots of the *macrotomia* not the leaves or stems. In the present invention the colours are extracted from the roots, radical leaves and basal stem portions of the plants belonging to the species of *Onosma*, *Amebia*, *Maharanga*, *Macrotomia*, *Lithospermum*, *Alkanna*, *Anchusa* of the family *Boraginaceae*. The roots contain much more colour than other parts only in the case of aforesaid genera. But the herbal colours are also obtained from other parts of the plants for examples seeds of *Bixa*, flowers of *Butea* and *Nyctanthes* etc. for cosmaceuticals.

We recognize that the Examiner objection is an objection of obviousness, and we have addressed this objection of obviousness adequately earlier. Yet, we would

BEST AVAILABLE

respectfully submit that there is no inspiration or clue from the each document to seek support for other documents or other areas of knowledge. Each document is stand-alone and there is no logical link between one document to another document. In short, both fall in different directions and the present invention provides yet another direction, which has no bearing on the citations. They are individual patents and there is no motivation to continue. Whereas, the instant invention is made with a progressive approach and not with hindsight.

The Examiner must appreciate that the cited arts are of years 1971 onwards. We have put several years of research to come out with the invention of the instant application. Had it been obvious for a person skilled in the art, then, would not the much-awaited instant work come out long back? The area of invention is a very 'hot' area of research. This is so because there great commercial demand for natural/herbal colors for lipsticks, etc. Further, these herbal colorants as cosmetics would not need medical prescription as would the creams of the prior arts.

Had it been obvious, the invention would have taken place immediately after the cited arts. There are several research groups in various parts of the world that are active in this area of research. Had it been so obvious, they would not have waited for so many years. The inventors have conducted multiple experiments of varying nature. It is only after several years of hard work involving much human involvement and inventive skills that the inventors have been able to achieve the desired results.

BEST AVAILABLE COPY



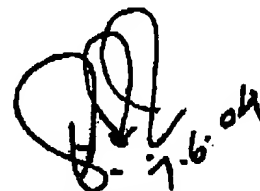
I hereby declare that all statements made herein of my own knowledge are true; and that all statements made on information and belief are believed to be true; and further that these statements are made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title XVIII of the United States Code and that willful false statements may jeopardize the validity of this Application for Patent or any patent issuing thereon.

Dated:

7.6.04

Place:

LUCKNOW



Dr. Palpu Pushpagandan

-31 AVAILABLE COPY